

### REMARKS

This is in response to the Final Office Action dated August 21, 2009 in connection with the above matter. All pending claims are presented for reconsideration and favorable action.

#### **Responding to Items 1 – 5**

It is found that Items 1 – 5 in the final Office Action are basically identical to Items 3 – 7 in the non-final Office Action.

However, as the applicants amended the claims in response to the non-final Office Action, those comments are believed to have been overcome. For Item 5 relating to the original Claim 4, since Claim 4 is deleted, the Examiner's comments are based on the wrong ground.

#### **Responding to Item 6**

##### (1) “**ZnSe or Ge** ATR probe” and “hollow fiber” in Claim 1

The applicants read Item 6 carefully. However, it is found that those statements on “**ZnSe or Ge** ATR probe” and “hollow fiber” are not considered by the Examiner, which is a distinct structural technical feature of the present invention over the prior arts.

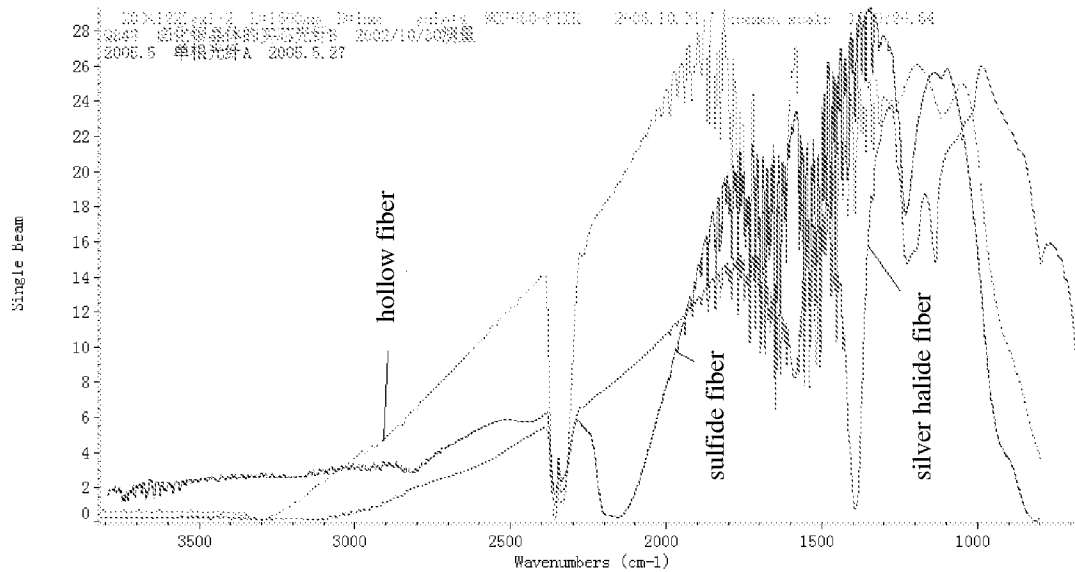
Hereunder is the quotation of the statements already present in the response to the non-final Office Action.

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Afanassieva requires a Silver Halide fiber used as the probe.

However, in the present invention, a **ZnSe or Ge** ATR probe is used and the fibers are all **hollow fibers** with multiple layers of **different coatings** on their inside walls. ...

The Applicant respectfully holds that the material of the probe and the structure of the hollow fiber cannot be anticipated without any inventive labor from Afanassieva, Eguchi, Stapleton, Dukor and Doyle's disclosures.



It can be seen that **hollow fiber** has the **best** infrared transmission performance from the above figure.

Doyle discloses a hollow metallic light guide 5 in Fig. 2. However, **this light guide 5 cannot be bent and would be non-applicable in the system disclosed by Afanassieva.**

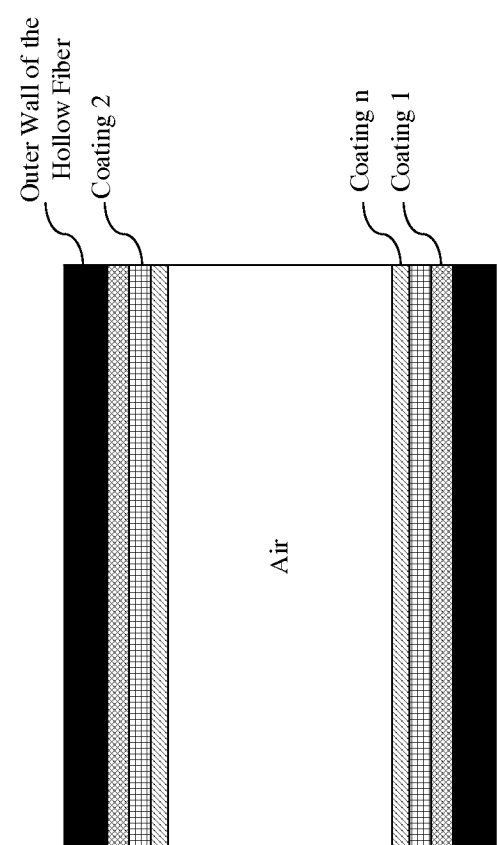
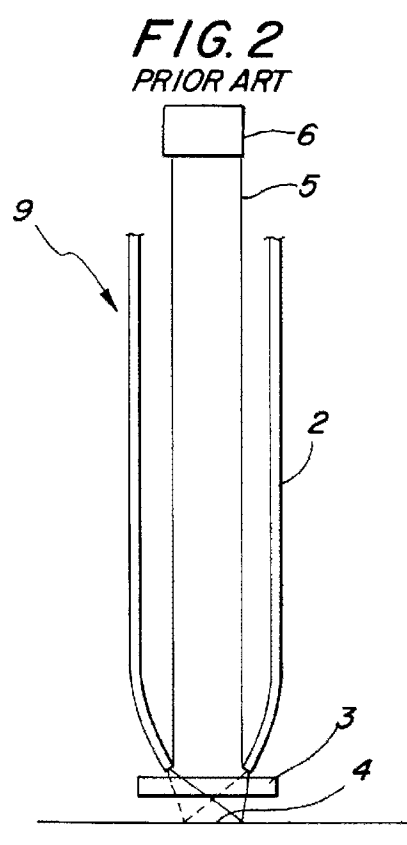
Therefore, the Applicant respectfully disagrees that Doyle's metallic light guide 5 corresponds to the hollow fibers in the present invention.

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(1.1) That is to say, (a) the hollow fiber (actually invented by the inventors of the present invention) will provide a good performance in the mid-infrared region superior to Afanassieva's invention using the Silver Halide fiber; and (b) the hollow metallic light guide 5 mentioned by Doyle does not correspond to or hint the hollow fiber of the present invention. The works of the applicants and Doyle are based on very different design.

As comparison with Doyle's disclosure, hereunder is provided the detail illustration (*cf.* Table 1).

Table 1

	hollow fiber used in present invention	metallic light guide 5 in Doyle's disclosure
Illustrations		<p><b>FIG. 2</b> <b>PRIOR ART</b></p> 
Flexibility	Flexible and bendable	non-bendable
Optical Performance	Used for mid-infrared region	As known by those skilled in the art, this hollow metallic light guide 5 can be used for collecting near-infrared light <b>ONLY</b>
Structure	Single Fiber	Used for fiber bundles ( <i>cf.</i> the claims)

(1.2) Additionally, it is also believed that **NONE** of Afanassieva, Eguchi, Stapleton, Dukor and Doyle discloses a **ZnSe or Ge** ATR probe. If this is not the case, the Examiner is solicited to clearly identify relevant sentences in these references.

Compared with Afanassieva's probe shown in Fig. 3 and described in paragraph [0048] (*cf.* Table 2), the **ZnSe or Ge** ATR probe is inventive and superior in performance.

Table 2

	ZnSe or Ge ATR probe in present invention	probes in Afanassieva's disclosure
Illustrations		<p>Fig. 3</p>
Materials	ZnSe or Ge	Silver Halide
Stabilities	Stable	As known by those skilled in the art, Silver Halide is light sensitive and will decompose shortly after being exposed to light.
Dimensions	<p>Small (about 5 mm in diameter)</p> <p>Flexible</p>	<p><b>self-conflicting:</b></p> <p>par. [0014]: <math>R_{\text{bending}} &gt; 10</math> to 100 fiber diameters (normal fiber diameter is around 1 mm)</p> <p>par. [0048]: small tip probes, typically 1 mm in diameter (Fig. 3b) inside a catheter 39 (Fig. 3d)</p> <p><b>However, Figs. 3b and 3d cannot fulfill the requirements described in par. [0014]. Otherwise, the diameter of the probe would be 10 – 100 mm. It is difficult to make it into a catheter.</b></p>

That is to say, Afanassieva's teachings on probe are not implementable, and thus it shall be understood as Afanassieva taught nothing on probe.

(2) “Gland” and “subcutaneous infrared spectrum” in Claim 1

According to the present specification and claims, the “gland” termed in the claims are all **subcutaneous glands**, such as mammary glands, thyroid glands and parotid and submaxillary glands, which are quite distinct from “kidney, stomach, lung and prostate” announced by Afanassieva in which “kidney, stomach, lung” are not glands, and “prostate” is in abdomen and thus is not a subcutaneous glands. It is also strange that Afanassieva **ONLY** shows his diagnosis of a skin cancer in Fig. 6 as the example to explain her invention (the skin cancer is exposed on the skin surface, which is neither inside the body as “breast, kidney, stomach, lung and prostate” announced by herself, nor subcutaneous as claimed by the present invention).

Thus, it may be concluded that Afanassieva’s invention cannot be applicable to **subcutaneous glands**.

Actually, Afanassieva can **ONLY** perform the in vitro diagnosis (“larger tissue segment” (Fig. 3a), “biopsies” (Fig. 3b), “minimal invasive diagnostics” (Fig. 3c), “endoscope or catheter” (Fig. 3d) in par. [0048]). In contrast, the present invention is used for in vivo non-invasive diagnosis (as explicitly discussed in page 3 of the specification amended for the US national phase).

(3) “Tumor database” in Claims 1 and 3

According to line 27, page 7 – line 12, page 8 of the original specification, “the establishment and judgment of the criteria about whether or not a tissue has pathologic changes is **statistically** determined on the basis of **accumulation of infrared spectral data of tissue** with respect to a certain number of healthy persons and patients. For example, **by statistical analysis on spectral data of a gland of a number of healthy persons and patients**, it is possible to determine the criteria with respect to normal and pathologic spectrum data of the gland and classify the degrees of the pathologic changes. Even though the infrared spectrum of the same pathologic change presents some regular variations among different testees, significant variations among individuals are not present. Accordingly, these regular variations can be databased into computer software to process the detection information. For example, it is possible to **program**

**database processing software for cases and pathologic changes such as hyperplasia of mammary glands to give the diagnostic results**".

*Thus, **ONLY** those results diagnosed according to this database can comply with the medical regulatory requirements. So, they may be called as medical diagnosis results. Otherwise, like Afanassieva, the measured result is compared with **ONLY** one normal picture to get a result. It is believed that this result cannot be called as a medical diagnosis result. Therefore, it is in a great possibility that Afanassieva's invention and the results cannot be approved by the Medical Administration Office.*

**(4) "Band widths" in Claims 6 – 13 and 15 – 22**

It is believed that **NONE** of Afanassieva, Eguchi, Stapleton, Dukor and Doyle discloses the diagnosis by using variations in band widths. If this is not the case, the Examiner is solicited to clearly identify relevant sentences in these references.

**(5) "Cleaning and sterilizing" in Claim 14**

In this step, many considerations must be involved, for example, the selection of the cleanser and disinfectant. The cleanser and disinfectant must be (a) harmless to the skin, (b) not corrosive and devastating to the ATR probe, and (c) not influencing the mid-infrared measurements (no residue left or the residue of cleanser and disinfectant shall not have any interference on the FT-IR spectra obtained after cleaning and sterilizing the equipment). These requirements would not be easily fulfilled and obvious for those skilled in the art.

As concluded, the Applicant respectfully requests the Examiner to reconsider the amended claims to be inventive over Afanassieva, Eguchi, Stapleton, Dukor and Doyle.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue, or comment, including the Office Action's characterizations of the art, does not signify agreement with or concession of that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment or cancellation of any claim

does not necessarily signify concession of unpatentability of the claim prior to its amendment or cancellation. Applicant reserves the right to prosecute the rejection claims in further prosecution of this or related applications.

In view of the above amendments and remarks, it is believed that the present application is in condition for allowance. Consideration and favorable action are respectfully requested.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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